

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 2005D-0199]

**International Cooperation on Harmonization of Technical Requirements for
Registration of Veterinary Medicinal Products (VICH); Draft Guidance for
Industry on Specifications: Test Procedures and Acceptance Criteria for
New Veterinary Drug Substances and New Medicinal Products: Chemical
Substances; Request for Comments; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability for comments of a draft guidance document for industry (#176) entitled "Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances" (VICH GL39). This draft guidance has been developed for veterinary use by the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). This draft VICH guidance document is intended to assist to the extent possible, in the establishment of a single set of recommended global specifications for new veterinary drug substances and medicinal products. It provides guidance through recommendations on the setting and justification of acceptance criteria and the selection of test procedures for new drug substances of synthetic chemical origin, and new medicinal products produced from them, which have

not been registered previously in the United States, the European Union, or Japan.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 30 days after publication in the Federal Register*], to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Comments should be identified with the full title of the draft guidance and the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine, (HFV-143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6956, e-mail: dbensley@cvm.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote the international harmonization of regulatory requirements. FDA has participated in efforts to

enhance harmonization and has expressed its commitment to seek scientifically based harmonized technical procedures for the development of pharmaceutical products. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development among regulatory agencies in different countries.

FDA has actively participated in the International Conference on Harmonization of Technical Requirements for Approval of Pharmaceuticals for Human Use for several years to develop harmonized technical requirements for the approval of human pharmaceutical and biological products among the European Union, Japan, and the United States. The VICH is a parallel initiative for veterinary medicinal products. The VICH is concerned with developing harmonized technical requirements for the approval of veterinary medicinal products in the European Union, Japan, and the United States, and includes input from both regulatory and industry representatives.

The VICH Steering Committee is composed of member representatives from the European Commission; European Medicines Evaluation Agency; European Federation of Animal Health; Committee on Veterinary Medicinal Products; FDA; the U.S. Department of Agriculture; the Animal Health Institute; the Japanese Veterinary Pharmaceutical Association; the Japanese Association of Veterinary Biologics; and the Japanese Ministry of Agriculture, Forestry, and Fisheries.

Four observers are eligible to participate in the VICH Steering Committee: One representative from the government of Australia/New Zealand, one representative from the industry in Australia/New Zealand, one representative from the government of Canada, and one representative from the industry of Canada. The VICH Secretariat, which coordinates the preparation of

documentation, is provided by the International Federation for Animal Health (IFAH). An IFAH representative also participates in the VICH Steering Committee meetings.

II. Draft Guidance on Chemical Substance

The VICH Steering Committee held a meeting in August 2004 and agreed that the draft guidance document entitled “Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances” (VICH GL39) should be made available for public comment. This draft VICH guidance addresses specifications, i.e., those tests, procedures, and acceptance criteria which play a major role in assuring the quality of the new veterinary drug substance and medicinal product at release and during shelf life. FDA and the VICH Safety Working Group will consider comments about the draft guidance document. Information collection is covered under OMB control number 0910–0032.

III. Significance of Guidance

This draft document, developed under the VICH process, has been revised to conform to FDA’s good guidance practices regulation (21 CFR 10.115). For example, the document has been designated “guidance” rather than “guideline.” Because guidance documents are not binding, mandatory words such as “must,” “shall,” and “will” in the original VICH document have been substituted with “should.” Similarly, words such as “require” or “requirement” have been replaced by “recommend” or “recommendation” as appropriate to the context. The draft VICH guidance (#176) is consistent with the agency’s current thinking on the new veterinary drug substances and medicinal products. This guidance does not create or confer any rights for or on any person and will not operate to bind FDA or the public. An alternative

method may be used as long as it satisfies the requirements of applicable statutes and regulations.

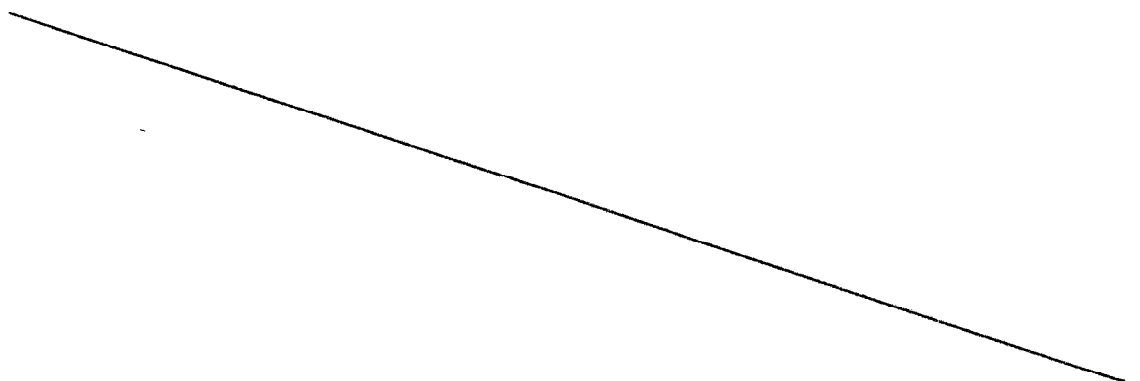
IV. Comments

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this draft guidance document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Comments may be submitted electronically on the Internet at <http://www.fda.gov/dockets/ecomments>. Once on this Internet site, select Docket No. 2005D-0199 entitled "Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and New Medicinal Products: Chemical Substances" (VICH GL39), and follow the directions.

Copies of the draft guidance document entitled "Specifications: Test Procedures and Acceptance Criteria for New Veterinary Drug Substances and



New Medicinal Products: Chemical Substances" (VICH GL~~39~~³⁹) may be
obtained on the Internet from the Center for Veterinary Medicine's home page
at <http://www.fda.gov/cvm>.

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Dated: 5/23/05

May 23, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

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